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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 21 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 90-OR-08. Section 18 Exemption for the use of Vinclozolin (Ronilan® 50W) on Snap beans to Control White and Gray Mold.
EPA Reg. No. 7969-53.
(No MRID #, DEB # 6361).

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To: D. Stubbs/Jim Tompkins, PM 41
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The Oregon Department of Agriculture requests a Section 18 exemption for the use of Ronilan 50W on green (succulent) snap beans to control white mold (Sclerotinia sclerotiorum) and gray mold (Botrytis cinerea).

Ronilan® FL fungicide (EPA Reg. No. 7969-53) is manufactured by BASF Wyandotte Corporation; the product contains 50% vinclozolin (3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione) as its active ingredient.

A maximum of 20,000 acres of snap beans will be treated with 20,000 (2 X 0.5 X 20,000) lbs of active ingredient.

Tolerances are established (40 CFR 180.380) for combined residues of the fungicide vinclozolin (3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione) and its metabolites containing the 3,5-dichloroaniline moiety in or on kiwi fruit, head and leaf lettuce, raspberries and strawberries at 10 ppm, stone fruits at 25.0 ppm, peppers (bell) at 3.0 ppm, Belgian endive tops at 5.0 ppm, and grapes at 6.0 ppm. No meat/milk tolerances are established. Numerous tolerances are pending, ranging from 0.05 ppm to 75 ppm. A feed additive tolerance has been established (40 CFR 186.1850) for vinclozolin in or on grape pomace (dry) at 42 ppm.

A Registration Standard has not been issued for vinclozolin.

No plant or animal metabolism studies were submitted with this request. However metabolism data were previously submitted in connection with PP# 5F3237/FAP#5H5465. For the purpose of this section 18 request (additional data for animal metabolism is needed for permanent tolerance), we consider the metabolism of vinclozolin in plants and animals to be adequately understood. The residues of concern are vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety.

90-OR-08 calls for two applications (0.5 lbs ai/A) of Ronilan® 50W (1.0 lb ai/A/season), with ground or aerial spray equipment, using 40 to 100 gallons of water/application. The first application is made at early or mid bloom and the second application 14 days later if needed. A 9 day PHI is stipulated.

The GLC (using ^{63}Ni electron capture detector) method described as Method I in PAM II is adequate for enforcement purposes.

No residue data were submitted with this Section 18, however, residue data were previously submitted in connection with PP#5F3237/FAP#5465 and 9F3762.

The available data from PP#5F3237/FAP#5465 reflect 2 applications at a rate of 1.0 lb ai/A/application, (2 lb ai/A/season; 2X the proposed rate for 90-OR-08). These data are summarized below:

rate of application lbs ai/A (# days between 2 appl.)	PHI days	Residues of vinclozolin PPM snap beans	snap bean forage
1.0 + 1.0 (13)	13	1.5	-------
1.0 + 1.0 (7)	17	0.6	18.2
1.0 + 1.0 (7)	16	0.3	4.2, 4.0
1.0 + 1.0 (14)	14	0.5	4.7
1.0 + 1.0 (14)	14	1.2	9.0
1.0 + 1.0 (10)	15	0.2	--------
1.0 + 1.0 (15)	9	0.6	3.0

Additional residue data submitted in connection with PP# 9F3762, reflecting a single application at 1.0 lb ai /A (1X the same rate proposed by 90-OR-08) are summarized below:

Type of application /1.0 lb ai/A location	PHI day	Residue of vinclozolin ppm snap bean	snap bean green forage	Dry forage	Cannery Waste
Ground/NC	14	0.6	3.7	8.1	---
Ground/NY	14	0.4	3.5	6.3	0.9
Ground/FL	14	0.5	9.7	17.4	---
Ground/MI	14	0.7	13.5	15.7	---
Ground/CA	14	2.4	50.8	164	9.8
Aerial/MI	14	0.6	7.6	7.3	---
Aerial/NY	14	0.8	15.1	32.6	2.5
Irrigate/OR	14	0.9	7.6	21.1	1.7
Irrigate/WI	14	0.7	4.3	14.2	---

Based on these data DEB concludes that residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety will not exceed 3.0 ppm in or on snap beans and 50.0 ppm in or on green snap beans forage, 164 ppm in or on dry forage and 10 ppm in cannery waste as a result of this proposed Section 18 use.

Meat, Milk, Poultry and Eggs:

Snap beans (seeds and pod) may be fed to cattle (20%), swine (25%) and poultry (15%) ~~of~~ their diet. Beans vines (bean forage) and hay are also used as animal feed items and may reflect up to 20 - 35% of the diet of dairy cattle. Bean vines and hay are considered to be under the control of the grower and thus subject to label restrictions against feedings. Grape

pomace (dry) may be fed to poultry and cattle at 5% and 30% of their diet respectively. If the diet of cattle consist of 35% bean forage, 20% bean seed and 30% grapes pomace, the maximum vinclozolin dietary burden to cattle would be 30 ppm. Similarly if the diet of poultry consists of 25% snap beans seed, and 5% grape pomace, the maximum vinclozolin dietary burden to poultry would be 3.0 ppm.

The results of a feeding study (PP#5F3237/FAP#5H5465) in which dairy cattle, and poultry were fed 3 ppm and 15 ppm vinclozolin for 28 days are summarized below:

Commodity	Feeding dose 3 ppm	15 ppm	30 ppm
Cattle milk	0.06	0.23	----
cattle fat	0.10	0.63	----
cattle kidney	0.22	1.19	----
cattle liver	0.75	2.89	----
cattle muscle	0.06	0.30	----
poultry eggs	0.10	0.39	0.95
poultry fat	<0.05	0.14	0.17
poultry kidney	0.10	0.39	0.55
poultry liver	0.08	0.58	0.88
poultry muscle	<0.05	0.12	0.18
poultry skin	0.05	0.13	0.19

Based on these data and a potential vinclozolin dietary burden of 30 ppm for cattle and 3.0 ppm vinclozolin for poultry, we conclude that secondary residues of vinclozolin are not likely to exceed 0.5 ppm in milk; 1.0 ppm in cattle fat, 0.5 ppm in muscle; 5.0 ppm in cattle liver and 2 ppm kidney; and 0.1 ppm in poultry eggs, muscle, liver, and kidney as a result of this proposed Section 18.

Conclusions:

1. The metabolism of vinclozolin in plants and animals is adequately understood. The residues of concern are vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety.

2. The GLC analytical method (Method I) described in PAM II is adequate for enforcement purposes. Analytical reference standards of vinclozolin are available from the EPA Repository.

3. Residues of vinclozolin are not expected to exceed 3.0 ppm in or on succulent snap beans , and 50.0 ppm in or on succulent

snap beans forages, as a result of this proposed use.

4. Residues of vinclozolin are not expected to exceed 0.5 ppm in milk; 1.0 ppm in cattle fat, and 0.5 ppm in muscle; 5.0 ppm in cattle liver, 2 ppm in cattle kidney; and 0.1 ppm in poultry eggs, muscle, liver, and kidney as a result of this proposed Section 18, provided a label restriction against feeding bean "hay" to cattle is in effect.

Recommendations:

TOX considerations permitting, DEB has no objections to this section 18, provided a label restriction against feeding bean "hay" to cattle is in effect. An agreement should be made with the FDA regarding the legal status of treated snap beans (succulent) in commerce.

cc: vinclozolin S.F., R.F., Section 18, Circ., F. Toghrol, PMSD/ISB, DRES (J. Kariya), R. Schmitt.
RDI: F. B. Suhre Section Head (3/21/90): E. Zager: ~~Acting~~ Deputy Chief (3/21/90):
TS-H7509C:DEB:F.Toghrol:F.T.:RM:802:CM#2:557-7887:3/21/90.